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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,524	06/27/2000	PETER JOHN BURNE	0769.00140	8239

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER

PADMANABHAN, KARTIC

ART UNIT PAPER NUMBER

1641

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,524

Applicant(s)

BURNE ET AL.

Examiner

Kartic Padmanabhan

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 154-168, 170-181, 211 and 212 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 212 is/are allowed.
- 6) ☒ Claim(s) 154-168, 170-181 and 211 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 168 and 170-181 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 168 recites a method for screening a sample of body fluid for first and second autoantibodies, wherein an antibody for one site on the antigen is immobilized, and an antibody for a different site on the antigen is in solution. However, in the presence of both the first and second autoantibodies, it appears that the first and second autoantibodies will bind to the two available binding sites on the antigen, thereby preventing the antigen from binding to both the antibody immobilized on the solid phase, as well as the antibody in solution. As such, the result would be a complex of antigen and both autoantibodies bound to the antigen in solution, such that no signal would be created. Further, in the presence of only the first autoantibody, the first autoantibody will bind to one site on the antigen, and the labeled antibody in solution will bind to the second site on the antigen, such that immobilized antibody on the solid phase cannot bind to the antigen, which will also result in no signal on the solid phase. Further, in the presence of only the second autoantibody, immobilized antibody on the solid phase will bind to the first site on the antigen, and the second autoantibody will bind to the other site on the antigen. In this situation, the

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complex immobilized on the solid phase cannot be detected because there is no label (which is present on the antibody in solution which cannot bind). As such, in the presence of either the first autoantibody or second autoantibody, or both, no signal will be present. Therefore, one will not be able to differentiate between which autoantibodies are present in the sample, thereby not allowing for the screening of first and second autoantibodies. The only situation in which the method as claimed seems operable is in the presence of neither first nor second autoantibody, in which instance, a normal sandwich assay will result producing 1 strong signal at the site of immobilized antibody. Taken as a whole, the nature of the invention lacks predictability, guidance, and working examples to screen for first and second autoantibodies, thereby requiring undue experimentation of one of ordinary skill in the art to practice the claimed invention.

3. Claims 211 and 154-167 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 211 recites a method for screening for distinct populations of first and second autoantibodies, wherein first and second antibodies to the antigen are both immobilized on a solid phase. In the presence of both first and second autoantibody, the first and second autoantibody will bind to the two antigenic sites, thereby preventing binding of the antigen to the antibodies on the solid phase, which will result in no signal. In the presence of neither autoantibody one nor autoantibody two, the results are more problematic. In theory, if neither of the autoantibodies were present, antibody on the solid phase specific for the first antigenic site would bind antigen. Antibody on the solid phase specific for the second antigenic site would also bind antigen in a distinct

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location, thereby resulting in two lines, which indicates the absence of both autoantibodies. However, as claimed, the method does not operate in this fashion. First, there is no positive recitation of labeling means that attaches to the antigen, which would allow detection. Rather, the claim only very generically recites labeling means to enable detection of autoantibodies, but has no explanation of in what manner this is done. Further, even assuming the labeling means were specifically recited to be attached to the antigen, as appears to be the case, since the method appears to be a flow through assay, what prevents a scenario in which all available antigen only binds to the first *or* second antibody on the solid phase, thereby providing only 1 line as a signal. In this case, there would be confusion as to if neither autoantibody were present or if one autoantibody were present, which scenario will now be discussed. In the presence of either first or second autoantibody (assuming again that label was recited to be attached to the antigen), the antigen would only be allowed to bind to one location on the solid phase, depending on which autoantibody were present to occupy the other binding site. In this case, only 1 line of signal would be formed on the solid phase; however, one would not be able to distinguish between the presence of one antibody or neither antibody, and one certainly couldn't tell which, if any, antibody was present. Taken as a whole, the nature of the invention lacks predictability, guidance, and working examples to screen for distinct populations of first and second autoantibodies, thereby requiring undue experimentation of one of ordinary skill in the art to practice the claimed invention.

Allowable Subject Matter

Claim 212 is allowed.

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Conclusion

Claims 154-168, 170-181, and 211 are rejected; claim 212 is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 571-272-0825.

The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kartic Padmanabhan
Patent Examiner
Art Unit 1641



CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP 1800 1641